REMARKS

Amendments to the Claims

Claims 1-141 are pending in the present application, with Claims 1 and 124 being independent. Applicant has amended Claims 1-2, 7-10, 12-13, 15, 20-23, 25-28, 30, 35-40, 42-43, 45, 50-53, 55-58, 60, 65-69, 71-72, 74, 79-82, 84-87, 89, 94-99, 101-102, 104, 109-112, 114-117, 119, 124-129, 131-132, and 134-140 herein. Applicant also has added new dependent claim 141. Support for the amendment can be found throughout the specification, and specifically for amendments to claims 1 and 124 and new claim 141 in at least paragraphs 23-25 of Applicant's published application. No new matter has been added.

Unless explicitly stated otherwise, none of the amendments to the claims were made for reasons substantially related to the statutory requirements for patentability. Furthermore, unless stated otherwise, the amendments to the claims were made simply to make express what had been implicit in the claims as originally worded and therefore are not narrowing amendments that would create any type of prosecution history estoppel.

Claim Rejections Under 35 U.S.C. § 103

In the Office Action, the Examiner rejected Claims 1-140 under 35 U.S.C. § 103(a) as allegedly being obvious over U.S. Patent No. 6,875,176 to Mourad et al. (hereinafter Mourad) in view of U.S. Patent No. 5,144,953 to Wurster et al. (hereinafter Wurster). See Office Action at 2-4. Applicant respectfully traverses this rejection.

Independent Claims 1 and 124

Applicant submits that the documents cited by the Examiner fail to teach or suggest, either alone or in combination, at least the feature of an evaluating unit, in communication with the ultrasonic transmitting/receiving unit, that determines a correlation coefficient $K_{1,2}$ of a time correlation between a first reflected ultrasonic wave $e_1(t)$ and a second reflected ultrasonic wave $e_2(t)$, the reflected ultrasonic waves corresponding to successively emitted ultrasonic pulses that are reflected in the target area in which a target object is located, and the correlation being

determined for a certain interval of time, wherein the correlation coefficient $K_{1,\,2}$ is determined by $\int_{T_1}^{T_2} e_1(t) * e_2(t)dt$, wherein the interval of time is determined by the points in time T_1 and T_2, and wherein the evaluating unit provides a signal related to the correlation coefficient $K_{1,\,2}$, as presently recited in independent Claim 1 and as similarly recited in independent Claim 124.

As Applicant understands, Mourad discloses diagnostic methods to assess physiological information about a target tissue. The target is treated with a first type of ultrasound pulse ("acoustic palpation signal"), which is generated from an ultrasound transducer 1. The palpation pulses cause an acoustic radiation pressure to the target resulting in a tissue displacement. The displacement is detected/measured by other ultrasound pulses ("interrogation pulses"). The interrogation pulses are generated from another ultrasound transducer 2 and have a pulse form, which is different from the acoustic palpation signals. The measured displacement is related to physiologic parameters like the intracranial pressure (ICP) or arterial blood pressure (ABP) by the usage of relations that were obtained by other measurements. However, Mourad does not disclose, teach, or suggest at least the feature discussed above for Applicant's independent claims 1 and 124. Wurster also does not cure the disclosure deficiencies of Mourad.

Additionally, as discussed below, the differences in the acoustic pulses and tissue interaction between the system of Mourad and lithotripsy are distinct such that it would not have been obvious to a person having ordinary skill in the art at the time of the invention to use the systems and methods of Mourad in lithotripsy, such as the lithotripsy disclosed in Wurster.

1. Differences in the acoustic pulses: In the Office Action, the examiner stated that Mourad does not disclose the use of a lithotripter but that conventional shock wave lithotripsy uses acoustic pulses of "extremely similar values and principles [compared in Mourad] to perform lithotripsy on an affected tissue." Office Action at 3. The examiner further stated that the differences between the "palpation pulses" and lithotripter shock waves would only be the higher amplitude of the lithotripter shock waves. See id. Applicant respectfully submits that these conclusion are not correct.

Mourad characterizes the "acoustic palpation signals" as (see col. 25, lines: 24 - 31): "Acoustic palpation signals may, for example, have a frequency of from 0.5 to 10 MHz, consist of long tone bursts of from 0.1 - 100 ms, consist of 1-100 pulses per second, and have a time averaged intensity of less than 100-1000 W/cm2, where longer pulses have lower intensities, for example." On the other hand, the acoustic pulses utilized in lithotripsy at the time of the invention included one single pressure phase with peak amplitude of 10 to 150 MPa and about 1 μs duration followed by a rarefaction phase of -2 to -10 MPa and of 1 to 5μs duration (see e.g., Coleman et al., "A survey of the acoustic output of commercial extracorporeal shock wave lithotripters," Ultrasound in Med. & Biol. 15:213-227, 1989 (cited in the accompanying information disclosure statement (IDS)). There were considerations to use double pulses in lithotripsy (see e.g., U.S. Patent No. 5,800,365); however, long tone bursts of 30,000 to 50,000 cycles as described in Mourad col. 42, l. 59-64 were not used in lithotripsy at the time of the invention. Accordingly, it would not have been obvious at the time of the invention to use the systems and methods described in Mourad for lithotripsy or in combination with conventional lithotripsy systems and methods, such as those disclosed in Wurster.

Furthermore, Mourad operates under different principles to generate pulses differently than conventional systems such that a it would not have been obvious at the time of the invention to use the systems and methods of Mourad with conventional lithotripsy systems and methods, such as those disclosed in Wurster. Mourad's generation of "palpation pulses" utilizes a function generator (see Mourad at Fig. 2), which emits sinusoidal waves of set frequencies and amplitudes, which are amplified. The electrical signal drives a piezoelectric material, which transforms the electric wave into an acoustic wave. Conventional lithotripters used different principles to generate shock waves at the time of the invention. Common to all of these conventional techniques was that an electric capacitor with high capacity is charged. With a fast switch, a high voltage pulse drives an electrode (electrohydraulic principle), a coil (electromagnetic principle), or a piezoelectric material (piezoelectric principle). By using a capacitor, which is discharged within a short time, a high amount of electric energy can be transferred into a short acoustic pulse of high amplitude. Accordingly, it would not have been obvious at the time of the invention to use the systems and methods described in Mourad for

lithotripsy or in combination with conventional lithotripsy systems and methods, such as those disclosed in Wurster.

2. Differences in tissue interaction: Mourad's tissue interaction also is different from conventional lithotripsy systems and methods such that it would not have been obvious at the time of the invention to use the systems and methods described in Mourad for lithotripsy or in combination with conventional lithotripsy systems and methods, such as those disclosed in Wurster. Mourad's palpation pulses create a "radiation force," which causes a reversible displacement (see Mourad Fig. 5A-C). The usage of long tone bursts (0.1 - 100 ms) is essential in Mourad, since it takes some time until the radiation force builds up, the tissue has reacted by a displacement, and echoes of interrogation pulses have been acquired. Thus, the proposed method of Mourad would not function when applying short pulses like shock waves in lithotripsy.

When a shock wave interacts with a concrement during lithotripsy, different effects occur (<u>see</u> Applicant's published application at para. 26): "An interaction mechanism between the shockwave and the concrement leads to a macroscopic movement of the concrement, especially when it has already been fragmented in part or even for the most part. Especially at the beginning of the treatment, when the concrement is still unfragmented to a substantial extent, other effects are prevailing, namely above all the shooting of fragments out of the concrement and the occurrence of cavitation bubbles around the concrement in the case of a successful hit...." For reference, a paper is cited in the accompanying IDS with more detailed information regarding such effects, including high speed camera sequences documenting the shock wave interactions with the stone (Bohris et al., "Hit/miss monitoring of ESWL by spectral Doppler ultrasound," Ultrasound in Med. & Biol. 29:705-712, 2003). As stated in the figure legend of Fig. 2 of the cited document, a 12 mm stone hit by a high amplitude shock wave did not visibly move. Long palpation pulses of low amplitude as described by Mourad do not cause stone fragmentation. To be non destructive is a basic requirement for a diagnostic procedure. When applying long pulses of increased amplitude to tissue, this application will lead to tissue heating rather than mechanical destruction. Those kinds of pulses are used in techniques known as HIFU

(high intensity focused ultrasound) or FUS (focused ultrasound surgery), which ablate, for example, tumors, thermally (for reference, see Zhou et al., "Measurement of high intensity focused ultrasound fields by a fibre optic probe hydrophone," J. Acoust. Soc. Am. 120:676-685, 2006, which is cited in the accompanying IDS). Thus, Mourad's tissue interaction also is different from conventional lithotripsy systems and methods such that it would not have been obvious at the time of the invention to use the systems and methods described in Mourad for lithotripsy or in combination with conventional lithotripsy systems and methods, such as those disclosed in Wurster.

3. Difference in signal processing: In Mourad, the radiation force causes a displacement. The usage of interrogation pulses and subsequent signal processing aims to detect the induced displacement. The displacement leads to a temporal shift of the tissue front echo of the received interrogation pulses (see Figs. 5 D-F of Mourad). The displacement is evaluated by normalized correlation of paired received signals (see Mourad at col. 41, l. 26-32).

In lithotripsy, the shock wave causes a more complex interaction than a tissue displacement. Therefore, measurement of tissue or stone displacement is not meaningful. The hit by a shock wave causes the echoes to show significant relative signal change (see Applicant's specification, Fig. 4). This change is not quantified by Mourad's processing. Thus, Mourad's signal processing also is different from conventional lithotripsy systems and methods such that it would not have been obvious at the time of the invention to use the systems and methods described in Mourad for lithotripsy or in combination with conventional lithotripsy systems and methods, such as those disclosed in Wurster.

Summary of Independent Claims 1 and 124

As discussed above, considerable differences in the acoustic waves applied to the body, the physical interaction between the applied acoustic waves and tissue or concrement, and the evaluation of received signals exist between Mourad's systems and methods and lithotripsy, such that it would not have been obvious to a person having ordinary skill in the art at the time of the invention to use Mourad's device and methods for diagnostic assessments of acoustic therapy

with the lithotripsy methods and apparatus of Wurster for the purpose of facilitating monitoring and control of lithotripsy. Accordingly, Applicant submits that independent claims 1 and 124 are patentable over the combination of Mourad and Wurster.

Dependent Claims

The remaining claims depend from one of the independent claims either directly or indirectly and are submitted to be patentable for similar reasons. The dependent claims also recite additional features further defining the claimed invention over the cited documents, and Applicant submits that the cited documents do not teach or suggest integrating those features into the presently claimed invention. Accordingly, Applicant requests separate and individual consideration of each dependent claim.

No Waiver

All of Applicant's arguments and amendments are without prejudice or disclaimer. Applicant has not addressed each specific rejection of the independent and dependent claims because Applicant submits that the independent claims are allowable over the documents of record, as discussed above. Applicant has not acquiesced to any such rejection and reserves the right to address the patentability of any additional claim features in the future.

CONCLUSION

Applicant submits the foregoing as a full and complete response to the Office Action. Applicant submits that this Amendment and Response places the application in condition for allowance and respectfully request such action. If any issues exist that can be resolved with an Examiner's Amendment or a telephone conference, please contact Applicant's attorney at 404.572.2809.

Respectfully submitted,

/William O. Isaacs, II/

William O. Isaacs, II
Reg. No. 44,165

King & Spalding LLP
34th Floor
1180 Peachtree Street, N.E.
Atlanta, Georgia 30309-3521
404.572.4600